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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/520,180
Filing Date: January 05, 2005
Appellant(s): NISHIKAWA ET AL.

Matthew L. Schneider
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/21/09 appealing from the Office action mailed 8/6/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon(10) Response to Argument

4,781,691	GROSS	11-1988
5,575,778	HARDT	11-1996

7,063,681	PEERY	6-2006
6,517,523	KANEKO	2-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 3, 4,5,21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (US 4781691). Gross discloses a stepped needle comprising a liquid container 40 capable of holding liquid therein; an injection needle 10 having a puncture section 20 capable of piercing a living body; a proximal end section 14 having outside and inside diameters greater than said puncture section; a tapered section 18; a base body 12 supporting the needle, wherein the tapered section and the puncture section protrude from the base body. The tapered section 18 facilitates passage of the needle through the body tissue (Col. 4, lines 29) See Figs. 2 and 6. Gross further discloses that the injection needle has a liquid introducing needle section that can communicate with the liquid container. See Fig. 2. The outside diameter of the proximal end 14 is 0.64-1.3 mm, the outside diameter of the puncture section 16 is 0.46-0.64 mm, the length from the puncture section to the tapered section is 6.4-19 mm (Col. 3, line 63 – Col. 4, line 8). The puncture resistance is inherently 7gf or less since the device has the same size and shape as applicants. Gross discloses that the tapered section 18 facilitates passage of the needle through the body tissue (Col. 4, lines 30-33).

3. Claims 1 and 4 differ from Gross in calling for the length of the tapered section to be 1.5 to 10 mm, and the tapered section to posses an outer profile forming an angle ranging from 0.5 degree to 1 degree and 20 minutes. Gross does not explicitly disclose these ranges, however Gross does disclose that the goal of the invention is to provide easy passage of the needle into human tissue. Gross achieves this goal by forming a tapered section in the needle having a small puncture resistance. Therefore, it would have been well within the skill of one of ordinary skill in the art to determine the optimal dimensions to achieve this goal. Applicant provides a graph in Fig. 8 of applicant's disclosure to provide support and criticality for the claimed ranges. However, upon close consideration, it has been determined that this graph does not render the invention non-obvious. The graph does not show that the entire claimed range has been tested, nor does is disclose the dimensions of the needle which it is tested against. It is well known that a reduced angle will provide a smaller puncture resistance, and therefore, this graph proves nothing that is not already known. In other words, the use of the claimed dimensions does not show any unexpected results. Furthermore, the length of the tapered section is merely a function of the diameter of the smaller section, the diameter of the larger section, and the angle of the incline there between.

4. Claims 1, 4 further differ from Gross in calling for the total length of the needle to be 5 to 40 mm. It is known in the art to adjust the length of a needle to meet the requirements of the procedure in which it is to be used. The total length of the needle may be adjusted by lengthening or shortening the proximal section without affecting the puncture resistance or any other critical features of the device. It would have been obvious to one of ordinary skill in the art

at the time of invention to modify the device of Gross to have any suitable length because it is beneficial to form a needle of a length to meet the requirements of the procedure.

5. Claims 7, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Hardt et al (US 5575778). Claim 7 differs from the teachings above in calling for the proximal end of the needle to include a second needle point. Hardt teaches a syringe having a needle 26 having a point at both the proximal and distal ends so that the proximal end of the needle can be inserted though the sealed septum of a container. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the needle of Gross to have a second point on the proximal end so that the needle can be inserted into a sealed container.

6. Claims 8-11, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Peery (US 7063681). These claims differ from the teachings above in calling for the puncture section to comprise a first facet having an angle of 8.5 degrees and a second facet having an angle of 18 degrees. Peery teaches a puncturing device having a puncture section 40 having a first facet having an angle of 5-45 degrees and a second facet having an angle of 10-60 degrees to provide minimal tissue trauma during insertion (Col. 4, lines 55-61; Col. 5, lines 7-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Gross to include the two facets as taught by Peery to reduce tissue trauma upon insertion.

7. Claims 12, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Kaneko et al (US 6517523). Claims 12, 18 differ from the teachings above in calling for the cross-sectional angle formed between the ridges of the needle point to be 129 degrees. Kaneko teaches a needle comprising a pointed tip having a cross-sectional angle formed between the ridges to be 115-135 degrees to ensure that the resistance force at the time of sticking is as small as possible (Col. 6, lines 45-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the needle of Gross to include a cross-sectional angle of 129 degrees as taught by Kaneko to ensure that the resistance force at the time of sticking is as small as possible.

(10) Response to Argument

Applicant's arguments have been fully considered and are not persuasive. Applicant argues that the examiner has not provided a clearly stated reason why the claimed invention would have been obvious over Gross. Gross discloses a needle including the features of the claimed invention, but fails to disclose the length or angle of the tapered section. Gross does not disclose that the tapered section has different dimensions than those claimed, but is silent on the matter. Gross explicitly discloses that the "tapered intermediate portion facilitates passage of the needle through body tissue" (col. 4, lines 29-31). The teaching is that a tapered section provided between a smaller diameter puncture portion and a larger diameter proximal portion provides a reduced puncture resistance thereby allowing for the benefits of both a larger diameter needle and a smaller diameter needle (col. 1, liens 55-65). One of skill in the art would know from this

use of a tapered section as well as from general knowledge of the needle art that the angle of the taper can be reduced to provide a reduced puncture force. One of skill in the art would also know that a balance must be struck between minimizing puncture force and preserving the integrity of the needle. Applicant is correct in asserting that one of skill in the art would know to that a tapered section having a very long very gradual taper would have an even lower puncture pressure than the tapered section claimed by applicant, however one of skill in the art would also certainly know that a needle of such a length would be of no use as it would lack the column strength to transmit the puncture force. The idea of incorporating a tapered section in a needle to facilitate passage of the needle into the body, in other words minimize the force required to puncture the tissue is well known in the art. As for the claimed length of the tapered section, Applicant has failed to provide criticality for this range as will be described presently.

Applicant has provided no criticality for the specific angle of the taper or the length of the tapered section. The claimed length of the tapered section ranges from 1.5mm to 10mm. That is a fairly large range considering that the length to be inserted into the body is 5mm to 40mm. Applicant provides a graph in Fig. 8 which shows the puncture force of the instant invention as compared to a needle having a larger taper angle (specification p. 22-24). However this does not provide criticality to the claimed range because it is a comparison between two needles only – a needle having a taper length of 1mm and a needle having a taper length of 3.5 mm, and the other parameters of the needles being the same, each representing a single value within the large claimed range. Applicant has shown the criticality of the dimensions of that particular needle only, and not the entire range. The graph and the included information provide no evidence that the claimed range is significant.

Applicant argues that there is no evidence of record that the claimed length of 1.5 to 10mm would have been recognized by one of skill in the art as a result-effective variable that would have optimized the ability of Gross' needle to pass through body tissue. Gross discloses a needle having similar dimensions and the same configuration as the instant invention. Gross discloses that the tapered section facilitates passage of the needle into tissue. One of skill in the art would know that the length of the tapered section could be varied to achieve any desired properties such as reduced puncture resistance as is disclosed by Gross, while maintaining the integrity of the needle. And furthermore, applicant has failed to provide criticality for the claimed range for the length of the tapered section.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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